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1653

PATENT
Customer No. 22,852
Attorney Docket No. 6832.0012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David J. BALLANCE et al.) Group Art Unit: 1653
Application No.: 09/832,501) Examiner: Hope A. Robinson
Filed: April 12, 2001)
For: ALBUMIN FUSION PROTEINS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated August 26, 2003, the Examiner required
restriction under 35 U.S.C. § 121 between the following groups:

- | | |
|-----------|--|
| Group I | Claims 1-21, drawn to an albumin fusion protein comprising a therapeutic protein X and albumin (SEQ ID NO: 18), class 424, subclass 192.1; |
| Group II | Claims 22-25, drawn to a method of treating a disease or disorder in a patient, class 514, subclass 12; |
| Group III | Claim 26, drawn to a method of extending the shelf life of therapeutic protein X, class 435, subclass 449; |
| Group IV | Claims 27-29, drawn to a nucleic acid molecule, class 536, subclass 23.4; |
| Group V | Claims 30-50 and 60, drawn to an albumin fusion protein comprising an interferon alpha polypeptide, classified in class 424, subclass 192.1; |

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- Group VI Claims 51-54, drawn to a method of treating a disease or disorder in a patient using the fusion protein comprising an interferon alpha polypeptide, classified in class 514, subclass 12;
- Group VII Claim 55, drawn to a method of extending the shelf life of an interferon alpha polypeptide, classified in class 435, subclass 449; and
- Group VIII Claims 56-59, drawn to a nucleic acid molecule encoding an albumin fusion protein comprising an interferon alpha polypeptide, classified in class 536, subclass 23.4.

Applicants provisionally elect to prosecute Group I, claims 1-21, drawn to an albumin fusion protein comprising a therapeutic protein X and albumin (SEQ ID NO: 18), with traverse.

According to MPEP § 803, there are two requirements that must be met before a proper restriction requirement may be made: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Office has failed to establish the second requirement set forth in MPEP § 803.

In the present invention, Groups I-IV relate to an albumin fusion protein comprising a therapeutic protein X and albumin. Groups V-VIII mirror Groups I-IV except that Groups V-VIII relate to an albumin fusion protein comprising an interferon alpha polypeptide. A search and examination of the subject matter of any one of Groups I-IV would necessarily encompass a search for the albumin fusion protein comprising an interferon alpha polypeptide of Groups V-VIII, and any additional search would not impose a serious burden upon the Examiner.

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It is therefore respectfully requested that the restriction requirement be reconsidered. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications on the non-elected inventions and/or to request rejoinder of appropriate claims once the subject matter of claims 1-21 is found allowable.

Applicants filed a Change of Correspondence Address on September 22, 2003.

Kindly direct all future correspondence for the instant application to:

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 25, 2003

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